UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS) (RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF DR. KATHLEEN SUTCLIFFE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rule

Academic Literature

The PSC respectfully files this motion to exclude the testimony of Kathleen Sutcliffe, Ph.D., an "organizational behavior expert." The PSC incorporates as if set forth in entirety the legal standards set forth in The Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard ("Rule 702 Standard Brief") as supplemented herein.

I. Introduction.

According to Dr. Sutcliffe, she was retained to address J&J's conduct and reaction to concerns—expressed since at least the 1970s—that Johnson's Baby Powder posed a risk to women who used it for feminine hygiene. (Ex. 1, Sutcliffe Rep. 3 ¶ 9.) Dr. Sutcliffe also claimed to "assess what Johnson & Johnson . . . knew—and when—about the alleged presence of asbestos" in its products. *Id*.

But her opinions on these questions are not reliable or admissible under *Daubert*, for three reasons:

- **First,** she lacks the requisite qualifications. Dr. Sutcliffe is wholly unqualified by education, experience or training to evaluate the evolving scientific and regulatory issues she professes to understand about whether J&J acted consistent with its duties relating to the safety of a consumer product regulated under the Food, Drug & Cosmetic Act (FDCA).

- **Second,** her so-called methodology is unscientific in the extreme. She employs a "qualitative" and "sensemaking" methodology to evaluate what J&J "knew – and when" about the safety of the product, but that is no methodology at all. Rather, it is a pretentious cover for cherry-picking evidence that supports J&J's litigation position, while ignoring (and not even reading) evidence that is harmful to J&J. And her methodology is not one that meets the traditional *Daubert* factors (testability, repeatability, known error rate, general acceptance). "Sensemaking" is a

cover story for what Dr. Sutcliffe really intends to do, which is to offer fuzzy opinions about J&J's good character in an untestable, unrepeatable way.

- **Third**, Dr. Sutcliffe's testimony lacks fit to the facts of this case. Incredibly, she opined that the sole period of potential safety issues relating to talc safety—what she called "disruptive ambiguity"—*ended* in the 1970s. She did not conduct her "research" or formulate opinions on what occurred inside J&J in the 1980s, 1990s, 2000s, and 2010s, when considerable debate in the scientific and regulatory communities continued on the link between talc and ovarian cancer.

Dr. Sutcliffe's opinion is a badly dressed-up retrospective view of cherry-picked events she found in the J&J-produced evidentiary record. Even if it were the product of a reliable methodology, Dr. Sutcliffe is not the witness to offer it, nor is this opinion relevant to the actual issues and time periods in this litigation. For all these reasons, Dr. Sutcliffe's testimony and opinions should be excluded.

II. Dr. Sutcliffe's overall opinion is an extraordinarily broad, general one.

Dr. Sutcliffe offers an extraordinarily broad opinion that touches on everything J&J knew, and whether J&J acted with the safety of women in mind. Or, in her own words:

> I have been asked to assess what Johnson & Johnson ("J&J") knew − and when − about the alleged presence of asbestos in its cosmetic talc products, and what actions it took to acquire this knowledge. In addition, I have been asked to assess the extent to which J&J's actions were consistent with an organizational commitment to the wellbeing of consumers.

(Ex. 1, Sutcliffe Rep. 3 ¶ 9.) At her deposition, she explained again that her charge was to "understand J&J, what they knew and when about the safety of its product, and whether or not the actions that they have taken to actively seek out scientific knowledge . . . are consistent with a company that cares about the well-being of its consumers." (Ex. 2, Sutcliffe Dep. 157:7–18.)

"Sensemaking"—she puts this forward as an organizational behavior that can be qualitatively measured—is the method Dr. Sutcliffe would offer to the Court as the basis of her opinions. While she claims that "studying sensemaking" is fully cognizable as an academic science, Dr. Sutcliffe also allows that doing so is "a challenging exercise [because] its interactive, emergent, and evolving aspects can be difficult to observe and capture." (Ex. 1, Sutcliffe Rep. 17 ¶ 46.)

"Sensemaking" is the process "for evaluating how new information enters an organization, how the organization interprets that information, and how the organization then chooses to act upon the information." *Id*. at 14 ¶ 42. Supposedly, "sensemaking is the process by which organizations answer the following questions: 'what's going on here?' and 'what do I do next?'" *Id.* And sensemaking is "an *ongoing* process." *Id*. Dr. Sutcliffe's entire report is couched in language about "sensemaking."

According to Dr. Sutcliffe, the expert in exhuming J&J's own historical "sensemaking," sensemaking is typically triggered by a period of "uncertainty, or

'disruptive ambiguity.'" *Id*. at 15 ¶ 43. Dr. Sutcliffe defined "disruptive ambiguity" in gauzy terms as the state of being that exists any time there are "multiple and conflicting interpretations of what's going on" inside an organization. (Ex. 2, Sutcliffe Dep. 107:17–108:2.) (Plaintiffs would observe that, under that definition, every person and organization on Earth experiences "disruptive ambiguity" at all times.) According to Dr. Sutcliffe, there is no real "black and white" way to determine if an organization is experiencing the right kind of "disruptive ambiguity." *Id*. at 108:3–24.

According to her, organizations may or may not collect information on the "disruptive ambiguity" and then attempt to fit that knowledge onto a "map" which reflects the organization's knowledge and plans. *Id*.

What Dr. Sutcliffe claims to be an expert in is judging whether J&J was any good at "sensemaking" when it encountered information about the risk of talcum powder and ovarian cancer. According to Dr. Sutcliffe, answering those broad questions required "an analysis of many decades of—of evidence and research." *Id*. at 114:18–115:9. And according to her, to do it right, "you would like to have a broad and rich understanding of what's happening in the environment." *Id*. at 25:6–14.

To assure the Court that she could have formed such an understanding, Dr. Sutcliffe claims to have had access to *every* document in "J&J's full global

production record in the J&J baby powder/talc" lawsuits, including more than 500,000 J&J documents, and according to her, she has had access to the bulk of these since 2019. *Id*. at 22 ¶ 59. Dr. Sutcliffe also claims that she requested depositions and trial testimony by J&J that continued to be given during the course of her assignment, as well as various public documents. *Id*.

Dr. Sutcliffe did not manually review all the documents available to her. Rather, she admits she relied on J&J's attorneys to feed her documents on various topics. *Id*. at 23 ¶ 61. This "sample was arrayed against my conceptual framework of sensemaking . . . to allow for scrutiny and revision of the study's constructs." *Id*.

This means that in performing her historical, retrospective review of J&J's organizational behavior, Dr. Sutcliffe did not define her document set first and stick with it. She admits that her process, which started with the documents fed to her by J&J's lawyers, "was also iterative," so that she could "confirm or disconfirm patterns." *Id*. at 23 ¶ 62.

Dr. Sutcliffe assigned her selected documents to various "bins" and "Topics." *Id*. at 24 ¶ 63. Documents were "binned" and she "leveraged these existing bins" and then performed a process that "served as an independent check on the binning." *Id*. These "intellectual bins," like her research as a whole, remained a moving target, and "the intellectual bins and resulting conceptual

framework guiding the research were refined" even as she performed it. *Id*. at 20 ¶ 55.

What Dr. Sutcliffe actually did after "binning" the materials available is hazy, and not well-defined in her report. She employed no quantitative methods at all; for example, she did not assign documents or the events described within them to any kind of pre-determined scoring metrics or rubrics. (Indeed, she couldn't, because her process was "iterative" and mutated throughout her assignment.) She did not use a testable or repeatable process. There is nothing in her report approaching anything like a rigorous formula, or balance scale, upon which a second researcher could place the same evidence and yield the same result. Dr. Sutcliffe's methodology was, according to her, an "established qualitative methodology . . . that is excellent for the kind of work," Ex. 2, Sutcliffe Dep. 19:16–22, but it was something she repeatedly struggled to actually explain in practice.

While she failed to explain what she did with the information she was fed and collected, at her deposition she was clear on the many things she did *not* do as part of her work. For example, she testified that "I wasn't analyzing the safety culture" at J&J. (Ex. 2, Sutcliffe Dep. 174:24–175:9.) She testified that "I was not studying the individual policies and procedures that J&J has." *Id*. at 177:2–15. She testified that she did not "stud[y] specific decision-making. I studied a broad range

of evidence, and I'm not looking at any one incident." *Id*. at 199:19–23. Nor did she study J&J's decision processes. *Id*. at 200:17–24. She "was not examining risk reduction measures." *Id*. at 242:18–23.

Dr. Sutcliffe opines that "sensemaking . . . is most visible or explicit in moments of uncertainty." (Ex. 1, Sutcliffe Rep. 42 ¶ 108.) While Dr. Sutcliffe was never able to clearly define this uncertainty, this "disruptive ambiguity" she was looking for, she was sure that for J&J, it was over by the end of the 1970s:

> Q. All right. So now you talked about the disruptive ambiguity in the 1970s relating to asbestos that was, in your opinion, resolved by the late 1970s, correct?
>
> A. Yes.

Id. at 109:1–5. She is *unequivocal* on this, that J&J's "confusion . . . over asbestos in talc" ended in "the 1970s," Ex. 1, Sutcliffe Rep. 42 ¶ 109; that J&J experienced "disruptive ambiguity [in] the early 1970s," *id*. at 64 ¶ 161; and again that J&J's sole period of "disruptive ambiguity" was in "the early 1970s," and that it was then "resolved," *id*. at 81 ¶¶ 190, 188. Accordingly, her research focus into all of J&J's "sensemaking" is exceedingly limited after the 1970s. This point will be explored further below.

Dr. Sutcliffe's ultimate conclusion about J&J was glowing:

> "Over the course of decades, Johnson & Johnson paid attention to knowledge in the external environment; it devoted attention and resources to the interpretation of

> that knowledge; and it took actions as a result of any new knowledge. This is behavior I would expect to see in an organization committed to the wellbeing of consumers."

(Ex. 1, Sutcliffe Rep. 81 ¶ 189.)

It was also sweeping. Dr. Sutcliffe credited J&J with "developing, validating, disseminating, and challenging a 'map' that codifies the existing scientific knowledge regarding the detection of asbestos in talc and the safety of talc." *Id*. at 81 ¶ 190. According to her, this map informs and controls J&J's "internal testing, its interaction with regulators," and "its research agenda;" and the "map" governs J&J's relations to "external stakeholders," "scientific research," regulators, and consumers. *Id*. Despite limiting her primary research to the 1970s period of "ambiguity," Dr. Sutcliffe's opinion somehow embraces all the years *since* the 1970s, as she has detected a "continued commitment to discussion" that continues, apparently, through today. *Id*.

Dr. Sutcliffe's opinion, therefore, is an all-purpose and good-for-all-times opinion that J&J is a good company that acts like it "committed to the wellbeing of consumers." *Id.* at 82 ¶ 192. That opinion is, however, wholly inadmissible.

III. Dr. Sutcliffe lacks the qualifications to offer any of her opinions.

Dr. Sutcliffe's Ph.D. is in "Organization Theory and Behavior." (Ex. 1, Sutcliffe Rep. Ex. A (curriculum vitae), at A-1 [PDF page 97].) She is currently a professor at Johns Hopkins University. *Id*.

Dr. Sutcliffe's CV and deposition transcript make plain that she lacks *any* scientific knowledge in the subject matter on which she attempts to opine. Over 60 pages of her 82-page report deal with asbestos, talc, talc testing, and talc mining. But she is no expert in mineralogy, geology, talc mining, talc testing, or microscopy. (Ex. 2, Sutcliffe Dep. 49:12–50:22.) Though she expects to opine on what J&J knew and how it responded to science, she admits that she is not an expert in that science. She is neither an expert in toxicology nor an expert in epidemiology. *Id.*; *id.* at 53:3–54:24. She's not even sure if she took a single epidemiology course. *Id*.

While she also weighs in on J&J's warnings, Dr. Sutcliffe admits she is not a regulatory expert and knows nothing about when a warning or instructions should be added to cosmetic products under the FDCA. *Id*. at 55:1–20, 154:9–157:6 ("I am not a regulatory expert"). She has never consulted with the FDA or any company regulated by the FDA. *Id*. at 57:15–58:6, 70:14–19. Nor is she familiar with the responsibilities of a consumer products company under the FDCA. *Id*. Though clear policies and procedures are part of her expertise, she has never written a policy or procedure relating to risk assessment or mitigation with respect to an FDA-regulated company. *Id*. at 58:7-59:16.

With respect to J&J, Dr. Sutcliffe admits that it never contacted her in the normal course of business for anything, and it does not employ her "sensemaking"

methodology internally. *Id*. at 44:20–45:20. Indeed, although she had access to over 500,000 documents and countless J&J employees, she never found a single time that J&J ever reached out—*to anyone*—to get a "sensemaking" consultation with a behavioral expert. *Id.* at 46:11–47:1. Surely, with access to J&J's entire production record, she would have searched for evidence that she was following in any J&J footsteps along the same path. So the relevance of her qualifications to J&J's business is obscure at best.

Not only does she not have expertise or experience in any of the areas above, Dr. Sutcliffe didn't educate herself on the responsibilities of a cosmetic manufacturer like J&J, or its obligations under the FDCA. *Id*. at 27:11–28:16. Indeed, while she knew that Johnson's Baby Powder was a cosmetic, she testified that she did not know that the product was subject to the Food, Drug & Cosmetic Act. *Id*.

Rule 702 requires that a proposed expert witness have "scientific, technical, or other specialized knowledge" in the field in which the expert proposes to testify. "An expert may be generally qualified but may lack qualifications to testify outside his area of expertise." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003). While the qualifications component may be applied liberally, the Third Circuit has "not pursued a policy of qualifying *any* proffered witness as an expert." *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998) (emphasis in original).

Dr. Sutcliffe's opinion should be excluded in its entirety because each subject on which she purports to opine requires the application of technical knowledge she *wholly* lacks.

Her opinions on "what Johnson & Johnson ('J&J') knew – and when – about the alleged presence of asbestos," Ex. 1, Sutcliffe Rep. 3 ¶ 9, require the application of knowledge about mineralogy, geology, or talc mining and testing. She goes into great detail on this topic, professing to have located inside J&J "an extensive assessment of talc sources," a sense that "J&J was . . . attentive to the external environment" and to "early concerns regarding the health effects of exposure to asbestos." *Id*. at 33 ¶ 89. But without the necessary scientific background in this field, she cannot opine as to whether J&J's assessment was "extensive," whether J&J was sufficiently "attentive" or not, and whether J&J did a sufficient job dealing with "the health effects." *Id*.

In another passage of her report, Dr. Sutcliffe opines that "J&J quickly acknowledged the need for a 'good report outlining talc and asbestos.'" *Id*. at 36 ¶ 95. Ten pages later, she draws upon that and other arguments to reach the conclusion that "J&J's initial response . . . illustrates a pattern of 'best practices' in the process of sensemaking." *Id*. at 46 ¶ 119. But Dr. Sutcliffe is no expert in toxicology, asbestos, or a corporation's regulatory duties under the FDCA in order to reach that conclusion.

As yet another example of Dr. Sutcliffe overstepping her expertise, she offers the opinion that J&J "refine[d] its own [talc] testing methodology, which was more rigorous than that adopted by the industry." *Id*. at 11 ¶ 35, 52–55 ¶¶ 131–37. Yet Dr. Sutcliffe is no expert on talc or asbestos testing, which she admits, and she has no particular qualification to understand whether J&J's test methods were more or less rigorous than the industry as a whole. (Moreover, her knowledge base—primarily documents self-selected by J&J—does not give her the factual basis to offer that opinion either.)

And as yet another example, Dr. Sutcliffe discusses how she grappled with "questions of . . . whether J&J did enough to warn users of the alleged health risks" in its products. *Id*. at 4–5 ¶ 12. Yet, without any qualifications in regulatory requirements, and given that she is not qualified on consumer warnings, how could she offer those opinions either?

Dr. Sutcliffe professes throughout her report and testimony to be examining J&J's "sensemaking" capabilities. But whatever "sensemaking" is, it is not a magic cloak to be thrown over any particular subject in order to qualify the "sensemaking" expert to discuss it. In a surgery malpractice case, a party may not call a non-medical expert on the "sensemaking" of the defendant in responding to the "disruptive ambiguity" during the surgery; that party's expert needs to be another surgeon. For Dr. Sutcliffe to offer all of the opinions that she does on J&J's

good or bad response to scientific papers, literature, test results, warnings, and regulatory scrutiny, Dr. Sutcliffe would need expertise in all those fields. She does not have it.

This is not a case where an expert's qualifications in the area are just "a little thin." *Waldorf*, 142 F.3d at 627. Dr. Sutcliffe has *no* qualification to offer testimony on these issues. She may have a captivating story to tell outside the courtroom about "sensemaking," but her opinions on all these technical, scientific matters should be excluded from the trial because she lacks qualifications to offer them.

IV. Dr. Sutcliffe's testimony is not the product of a reliable methodology under *Daubert* or Rule 702. Her methodology appears to be made up to reach the desired conclusion.

By her own standard, Dr. Sutcliffe's charge was to evaluate the entire record of J&J's response to evidence of asbestos contamination in its talc products and determine if J&J's "sensemaking" produced a sufficiently rich "map." By her own admission, that would require an analysis of "what was said and done in the medical and scientific community and by other stakeholders and what they did at the time." (Ex. 2, Sutcliffe Dep. 22:18–23.) It would require "an analysis of many decades of—of evidence and research" to reach that necessary "broad and rich understanding of what's happening in the environment." *Id*. at 114:18–115:9, 25:6–14.

These aren't Plaintiffs' standards: they are Dr. Sutcliffe's own benchmarks for conducting a reliable "sensemaking" analysis. But Dr. Sutcliffe violated her own methodology throughout her work. That renders her opinions inadmissible because they are not "the product of reliable principles and methods." Rule 702(c). Rather, her report demonstrates cherry-picking to the extreme.

For example, Dr. Sutcliffe nakedly ignored—and in many cases did not even read—significant evidence on talc and ovarian cancer after 1980, including J&J's responses to that evidence.

According to Dr. Sutcliffe, the only period where there were genuine questions relating to asbestos in talc was in the 1970s. As cited above, she testified that "by the end of the 1970s, the [disruptive] ambiguity was gone. Testing had been established. Multilevels of testing had been established." (Ex. 2, Sutcliffe Dep. 39:13–40:10.)

And according to her, with the adoption of talc testing in the mid-1970s, Dr. Sutcliffe's period of "disruptive ambiguity" ended. *Id.* at 109:1–5. So did her research focus. Nearly 50 pages of her report describe the 1970s era. (Ex. 1, Sutcliffe Rep. 27–64, and others.) As she documents, J&J's "map" of information was fixed by the 1970s. *Id*. at 65 ¶ 162.

Though she admitted that, beginning in the 1980s, there were dozens of studies questioning if talc was a potential ovarian carcinogen, Dr. Sutcliffe testified

that "I don't know that I can say that for sure" whether that information would be sufficiently "disruptive" to spur J&J back into action. *Id*. at 109:11–19. Her testimony was that the publication of such information "can be or it might not be." *Id*. at 110:18–21. (Query: if she cannot opine on whether the post-1970s period was "disruptive" and "ambiguous," how can she be so sure that the 1970s period *was*?)

Dr. Sutcliffe's testimony was that, after the 1970s, there were "long periods where there has not been disruptive ambiguity, . . . where things have—have been relatively stable." *Id*. at 204:13–22. But despite her purportedly extensive knowledge base of over 500,000 J&J documents—which she testified a good researcher would need—Dr. Sutcliffe was unable to name these "long periods" of time where the knowledge base was "stable."

> Q. What period is that where there's been no concern about talc?
>
> A. I would say between—I mean, I don't know that I could say for sure, but after the, you know, after the disruptive ambiguities of the 1970s, early on I think that there was—it was pretty stable once the multilevels of testing had been established at J&J that things went—went along.
>
> Q. Okay. And then there ever come a time where disruptive ambiguity picked up again?
>
> A. You know, I haven't been thinking—I can't sit here and answer because I haven't thought about it that way.

Id. at 204:23–205:12.

There is a reason that she can't analyze or perform her "sensemaking" and qualitative" methodology to the post-1970s evidence—*she simply didn't read or review it in any meaningful way.*

At her deposition, to mask her failure to consider information, she deflected even simple questions relating to how and whether J&J reacted to suggestions that it reduce risks to consumers through warnings and design changes to Johnson's Baby Powder by saying that she simply didn't read those suggestions:

> Q. . . . [Y]ou are aware that during the course of those studies [after the 1970s] that recommendations were made to the company to do the things that we talked about before: warnings, changing to cornstarch, instructions to women not using—not using talc in their—in their private areas, to do additional studies.
>
> You remember all of those, correct?
>
> A. Again, I did not do a review of all of the scientific literature because I'm not an epidemiologist and I'm not . . . opining on that today.

Id. at 35:7–24. When pressed further, she admitted that she did not review or consider or even address what was being recommended by independent scientists to J&J *in real time* as part of her "sensemaking process."

> Q. I will show—I promise you, I will show you studies where recommendations were made about—of what the company ought to do, as part of sensemaking process, to understand what was going on at the time in real time. I will show you those documents.

> But as a general matter, do you understand that there were recommendations made to warn to change to cornstarch [or] study?
>
> A. I answer again that I have not done a systematic analysis of all the literature . . . with respect to cancer, ovarian cancer.

Id. at 38:3–16. This is an example of Dr. Sutcliffe wholly refusing to engage with external contacts J&J received about its products and their safety—something which, again, according to her *own* definition of "sensemaking" is something that good sensemakers must do.

Here are three specific papers that Dr. Sutcliffe did not analyze or discuss in her report. The first is from 1992, Harlow et al., *Perineal Exposure to Talc and Ovarian Cancer Risk*, 80 Obstetrics & Gyn J. 19 (July 1992). (Ex. 3, Sutcliffe Dep. Ex. 13.) This paper recommended that "given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in general hygiene, particularly as a daily habit." *Id.* at 26. Surely, this would have constituted an important communication from an "external stakeholder" that would have "disrupted" J&J's knowledge "map."

But Dr. Sutcliffe didn't know anything about it:

> Q. All right. Do you have any evidence that they reached out to speak to Dr. Harlow?

> A. I have—I don't know that they did or that they didn't.
>
> Q. Do you know whether or not they said, "You know something? Maybe that's a good idea. Let's get our various committees and people together and see whether or not we need to either advise women not to use talc as in genital hygiene or maybe switch to cornstarch."
>
> Have you seen anything like that in response to this in the medical literature at the time? Did you see it?
>
> A. I—I can't say that I did or that I didn't. . . .

(Ex. 2, Sutcliffe Dep. 214:12–219:4, 220:17–24.)

Another important paper was Cramer et al., *Genital Talc Exposure and Risk of Ovarian Cancer*, 81 Int'l J. Cancer 351 (1999). (Ex. 4, Sutcliffe Dep. Ex. 17.) The authors wrote that:

> We estimate that avoidance of talc in genital hygiene might reduce the occurrence of a highly lethal form of cancer by at least 10%. Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex. Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.

(Ex. 4 at 356.) The Cramer paper was, in Dr. Sutcliffe's own lexicon, another message from the scientific community and something that J&J should have incorporated into its "map." But Dr. Sutcliffe, after being shown this passage,

testified that she did not take this 1999 publication into account in her analysis and she did not find any reaction by J&J to this external stimulus:

> Q. . . . Other than being aware, would you tell me whether or not there was any discussion [at J&J] about whether on balance warnings, instructions or perhaps a change in design ought to—ought to occur?
>
> A. I was not looking at—at a single event or whatever. I'm looking at J&J's pattern of actions over time.

(Ex. 2, Sutcliffe Dep. 233:16–23.)

> Q. As you sit here today, do you remember seeing any discussion in that 15-year period [through 1999] about whether or not you ought to switch—J&J ought to switch or withdraw its product or at least put a warning label on it?
>
> A. . . . I can't say whether they did or they didn't because I wasn't looking at that.

Id. at 234:24–235:10; 232:20–21 (identifying 1984 to 1999 as the 15-year period).

A third paper was Mills, et al., *Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California*, 112 Int'l J. Cancer 458 (2004). (Ex. 5, Sutcliffe Dep. Ex. 18.) Here, the authors have written:

> [G]iven the suggestive though uncertain role of talcum powder and EOC found in epidemiologic studies, including the present study, users should exercise prudence in reducing or eliminating use. In this instance, the precautionary principle should be invoked, especially given that this is a serious form of cancer, usually associated with a poor prognosis, with no current

> effective screening tool, steady incidence rates during the last quarter century and no prospect for successful therapy. Unlike other forms of environmental exposures, talcum powder use is easily avoidable.

(Ex. 5 at 464.) That would have made it a third stimulus to J&J and, if J&J did not already have this information on its mental "map," it certainly should have provoked some "disruptive ambiguity" among J&J's scientists. Dr. Sutcliffe again testified, however, that she was unmoved and uninterested:

> Q. Is any part of that untrue at the time? Not with hindsight, but looking at it like right at that snapshot in time in 2004, is any part of that not true from your perspective?
>
> A. I'm just—I see what's written here. I can't say whether it's true or not true. It is what the researchers wrote.
>
> Q. Okay. This isn't referred to in your—in your sensemaking report, is it?
>
> A. I wasn't looking at—number one, I've already said that I wasn't looking at a systematic analysis of all the studies I looked through.

(Ex. 2, Sutcliffe Dep. 238:14–239:2.)

Regarding all these and other scientific recommendations from the 1990s into the 2010s, Dr. Sutcliffe admitted that she neither considered them nor looked for a J&J response:

> Q. We saw it from Mills. We saw it from Terry. We saw it from Harlow. We saw it from Cramer. We saw it from all these people talking about: Maybe it's a good idea to take risk reduction measures and

perhaps avoid the use of talc.

Do you see that?

. . .

A. They said what they said.

. . .

Q. You have not seen any internal analysis from J&J applying any standard metric to determine whether or not they should change to cornstarch or perhaps issue a warning?

A. I did not study J&J's individual decisions related to that issue.

(Ex. 2, Sutcliffe Dep. 246:6–247:7; 248:5–10.)

Recall Dr. Sutcliffe's sweeping conclusions—that *at all times,* "J&J's actions following the disruptive ambiguity of the early 1970s are consistent with an organization that seeks to challenge, and strengthen, its understandings through active engagement in sensemaking." (Ex. 1, Sutcliffe Rep. 64 ¶ 161.) Not only that, but according to her, J&J's good conduct and "commitment to a sensemaking process" permits it to "respond to future disruptions." *Id*. Yet Plaintiffs identified three important academic studies—out of dozens of others—and Dr. Sutcliffe had *no evidence* of J&J's response (or lack of a response) to any of them. She further admitted she had *no evidence* that J&J chose to take a retrospective look at the evolving science. How can she possibly reach her conclusions from this evidence base? She can't.

* * *

Not only did Dr. Sutcliffe fail to register any J&J response to these *outside* stimuli, she missed several important *internal* discussions where J&J considered, but rejected, learning more about the talc/cancer link. Dr. Sutcliffe knew nothing about them.

In 1999, the American Cancer Society (ACS) and other groups recommended that women use cornstarch powder instead of talcum powder. (Ex. 6, e-mail chain including ACS press release (Jul. 7, 1999).) They wrote: "Until additional information is available, women may wish to consider avoiding [talcum powder] or substituting cornstarch-based powders that contain no talc." *Id.* at 1. In response to that recommendation, J&J employees internally pondered whether they should "accellerate[] shift from talc to cornstarch." *Id*. When confronted with the ACS recommendation and evidence that J&J had actively considered shifting from talc to cornstarch in the 1990s, Sutcliffe had no idea that this shift to a safer alternative was proposed, or that it was even considered:

A. I see what's written. I can't divine exactly what they were meaning.

Q. Because you didn't look, did you?

A. I—I don't recall whether I saw this or didn't see this.

(Ex. 2, Sutcliffe Dep. 253:20–24; *see also* 249:5–257:2 (entire passage discussing Ex. 6).)

In fact, she didn't discover through her "sensemaking" methodology that J&J knew about this important external recommendation—or J&J's lawyers didn't tell her. It was clear that she didn't study it at any time:

> Q. Okay. In fact, you know—do you know that in 1999 to 2000 the company considered and rejected switching to talc and cornstarch for reasons that we have not been able to figure out?
>
> **A. I was—I did not study a single decision.**
>
> Q. All right.
>
> A. I was studying J&J's pattern of actions over decades.
>
> Q. Well, we've talked about pattern of—pattern of publications over decades. 1994, 1992, 1999, this in 1999, 2004 were the Mills, and 2013 Terry.
>
> This wasn't one isolated moment, this was a continuum, correct?
>
> A. It was years. I don't know that it's a continuum.

Id. at 254:1–17.

As part of her methodology, Dr. Sutcliffe did not know—or care to know—that J&J didn't study the safety of its talcum powder, even though others recommended that it do so from at least the 1990s. For example, J&J sponsored a study by Gross and Berg entitled *A Meta-Analytical Approach Examining the*

Potential Relationship Between talc Exposure and Ovarian Cancer, 5 J. Exposure Analysis & Environ. Epidemiology (1995). (Ex. 7 at 194 (sponsorship acknowledgment).) The authors surveilled the landscape of literature, and their paper clearly stated that "the results of the meta-analyses do suggest the possibility of an increased risk of ovarian cancer due to perineal talc use. Further research in this area is warranted by these results." *Id*. at 193.

Not only did Dr. Sutcliffe not know of this study, she didn't know that J&J never performed the further studies the J&J-sponsored scientists suggested**:**

> Q. Okay. So the questions in this J&J-sponsored study, they acknowledge longstanding questions about the safety of talc and they say additional studies need to be conducted, but the evidence so far supports the association. True?
>
> **A. I see what's written here. I have not studied this. I just see what's written.**

(Ex. 2, Sutcliffe Dep. 227:18–228:2; 225:7–229:24 (entire discussion of Ex. 7); *see also* 290:15-291:8 ("I have not done a systematic analysis of the literature").)

Dr. Sutcliffe was also not aware that in 1995, J&J scientists actually forwarded a study which, in their view, would definitively answer the question of whether talc was associated with ovarian cancer. (Ex. 8, internal memo (Jan. 24, 1995).) This proposed study was described as a "well-controlled, potentially significant study which should replace all others as the definitive treatise on this

issue." *Id*. Dr. Sutcliffe could not recall ever having seen that document either. (Ex. 2, Sutcliffe Dep. 330:15–336:23.)

Dr. Sutcliffe did not know about this proposal—the "definitive" study on the question—or apply any "sensemaking" as to what the study was:

> Q. Okay. Let's—okay. So let's expand it. Let's add a hundred thousand dollars just for giggles. Okay? Let's make it a $500,000 study. It would have been done by 1998.
>
> Have you seen the results of that study?
>
> A. **Again, I did not look at a specific—I didn't look at specific studies.**

Id. at 335:14–21. Nor did Dr. Sutcliffe know why a J&J product liability attorney was on the committee to review that study:

> Q. Does that seem odd to you that a product liability lawyer, as somebody who's involved in safety analysis for organizations, a product liability lawyer would be involved in drafting a definitive epidemiology to study a safety issue?
>
> . . .
>
> **A. I have no idea. I mean, yeah.**

Id. at 336:13–23. She admitted: "I don't know whether the study was done." *Id*. at 338:8–12. It wasn't.

Similarly, Dr. Sutcliffe didn't know or consider whether J&J performed any other systematic review of the scientific evidence on the talc and ovarian cancer question:

Q. My question was: Had you seen prior . . . [to] 2019 J&J performed any kind of comprehensive review of the epidemiology studies all in one place like Health Canada did?

Not paying attention. Not interacting. I'm talking about something where the scientists sat down together and did a comprehensive review like Health Canada did.

. . .

A. I know that J&J was following the scientific literature.

Q. Not my question, respectfully.

Had you ever seen a document where J&J actually did a comprehensive review?

A. I have—I can't say that I did or I didn't. So.

Id. at 361:8–362:2.

* * *

An expert opinion admissible under Rule 702 rests on "sufficient facts or data." Rule 702(b). It is the product of reliable principles and methods. Rule 702(c). And it rests on "good grounds," including an adequate factual basis to support it. *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017). To be admissible, the opinion should rest on determinations fully "based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)).

Dr. Sutcliffe's opinions are not reliable or admissible under these standards. She offers evidence of J&J's good behavior and adequate "sensemaking" at all times, but her evidence base is sorely limited, if not null, under her own wholly unsupported assertion that only the 1970s constituted a period of "disruptive ambiguity" leading to "sensemaking," after which everything quieted down for "long periods" she could not precisely identify. (Ex. 2, Sutcliffe Dep. at 204:13–22.) This is not good science. This is an academic using a dowsing rod to find the "right" evidence without knowing why.

She either ignored, was not fed by J&J's lawyers, or failed to locate on her own, the J&J response to all of the studies and external stimuli discussed above—as well as others. Her blinkered focus on 1970s talc test procedures which she is not qualified to understand cannot serve as an adequate basis to offer her conclusions. By not providing the Court with a methodology that is repeatable, let alone comprehensible, she gives only her "subjective belief." *In re Paoli*, 35 F.3d at 742. That is not enough under *Daubert* and Rule 702.

Further, Dr. Sutcliffe's report contains important standards for conducting research like hers—standards she set for herself, in her own words. She wrote that "'[g]ood science' in the field of organizational science involves a careful analysis." (Ex. 1, Sutcliffe Rep. 13 ¶ 40.) "It avoids cherry-picking, bias, inappropriate extrapolation, and broad generalizations about organizations . . . ." *Id*. Bad

research, in her words, "fail[s] to discuss or consider explanations that rival the narrative/conclusion" and "fail[s] to discuss or consider limitations in making generalized conclusions based on the sample data relied on." *Id*.

By not locating or contextualizing important events in J&J's history with talc, *Dr. Sutcliffe violated her own methodological rules.* "Inappropriate extrapolation?" Dr. Sutcliffe focuses on events in the 1970s—solely—to reach her bald conclusion that "J&J: . . . Actively investigated and responded to concerns about the safety of its baby powder products." (Ex. 1, Sutcliffe Rep. 6 ¶ 17.) "Broad generalizations?" Her report is full of commentary about J&J's "active" engagement with the science, yet she lacked any knowledge of several external signals to J&J *from* that science—she had no information *at all* whether J&J had responded to the Harlow, Cramer, or Mills studies. Bad science "fails to consider explanations that rival the narrative/conclusion"? Dr. Sutcliffe's conclusion was that J&J actively investigated its talc/asbestos problem, but she did not even *know* about several points where J&J could have learned more and chose not to.

Dr. Sutcliffe also ignored her own rules for corporate behavior that she has testified to in other litigations. In the *Deepwater Horizon*/BP oil spill case—where she testified for defendants, and was also struck on *Daubert* grounds—she opined on the need for *clear* policies and procedures "that reflect their commitment to safety." *Id*. at 171:17–172:6 (more generally, 167:20–176:9) (discussing Ex. 9,

Sutcliffe Dep. Ex. 6, excerpt of her *Deepwater Horizon* report). Yet, when asked about those same policies *in this case*, Dr. Sutcliffe demurred, testifying that "I was not analyzing the safety culture of J&J over time." Id. at 175:10–176:1.

When pressed, she was unable to identify a single J&J policy or procedure before 2017 that would guide it in decision making regarding safety of cosmetic products:

> Q. Okay. And so now my question is this: Have you seen a single policy and procedure in place at either Johnson & Johnson or Johnson & Johnson Consumer companies—it changed over time—which governed how to analyze a safety question when the issue arises?
>
> It's a yes or no question.
>
> **A. I was not studying that. I looked at policies and procedures, but my role was different.**
>
> Q. Okay. My question was: Did you see it?
>
> **A. I have to say, I don't recall what I saw or didn't see.**

Id. at 180:15–181:4; *see also id*. at 185:15–20 ("I can't say that I have or I haven't" seen a policy dealing with risk mitigation of risk assessment).

What Dr. Sutcliffe has done is not science. It is willful ignorance in the guise of science. Her *true* methodology appears to have been:

1. State that only "disruptive ambiguity" triggers "sensemaking" (whatever that means).

2. State that "disruptive ambiguity" is hard to spot and is not exactly "black and white." *Id*. at 108:3–24.

3. Find, without showing any of her work, that there were "long periods where there has not been disruptive ambiguity." *Id*. at 204:13–22.

4. Willfully ignore the evidence that came into J&J during those "long periods."

5. Declare that J&J did a great job being "very active" reacting to and managing the limited data in times of "disruptive ambiguity" onto its "map" of knowledge "over decades." *Id*. at 325:17–326:7.

This is gobbledygook. It may be interesting fodder for an academic talk. But it is not science and it is not admissible under the Federal Rules of Evidence.

V. Dr. Sutcliffe's opinions related to asbestos testing should be struck entirely.

As set forth above, Dr. Sutcliffe's 82-page report devotes a scant 8 pages—primarily pages 65–73—to the ovarian cancer evidence from the 40 years between 1980 and 2019. She devoted the great bulk of her "sensemaking" report and its appendices to talc testing and asbestos testing methodologies of the 1970s.

And she attempted to offer written opinions on the strength of those tests and J&J's commitment to women. For example, she wrote "it is my opinion that J&J:

. . . Relied on scientific knowledge and evidence, including a rigorous testing program, to verify the safety of its baby powder products." (Ex. 1, Sutcliffe Rep. 6 ¶ 17.) And she opined that, using "[i]mproved methods that emerged in the mid-1970s . . . J&J actively worked with the industry" to "make sense" of asbestos findings in its products. *Id*. at 55 ¶ 138.

Dr. Sutcliffe—no mineralogist or toxicologist or testing expert—has no business offering any such opinions regarding the "rigor" of J&J's test methodology. And when pressed at deposition on the basis of her asbestos-related opinions, she quickly demurred that she either "was not an expert" or "didn't study" those very issues.

For example, she disclaimed any knowledge of the sensitivity of J&J's asbestos testing:

> Q. . . . But based upon everything that you know, distilling it in its most clear form, is the testing methodology used by J&J—this really is a yes or no question—a hundred percent sensitive for the detection of asbestos? 100 percent.
>
> . . .
>
> **A. I am not opining on testing or sensitivity, reliability or validity of the testing.**

(Ex. 2, Sutcliffe Dep. 391:9–18.)

She disclaimed knowledge regarding the meaning of asbestos levels:

Q. Okay. So you would agree with Dr. Hopkins that there's a difference between saying something is asbestos-free and something saying that there's no detectable asbestos, correct?

A. Again, I am not a toxicologist, and I am not opining on that.

Id. at 396:4–10.

She disclaimed all knowledge about how much talc J&J has sold was actually tested for asbestos:

Q. Okay. Do you have any idea how much talc was actually tested using the testing methodology that they used?

A. Again, I'm not—I know the tests but, no, I'm not—**I haven't examined that**.

Q. Would it surprise you that less than 2 teaspoons of talc has been tested over that 50-year period?

A. Again, I'm not—

Q. You don't know that?

A. I—I don't know that. I'm not opining on those issues.

Id. at 398:9–22.

She disclaimed all knowledge of information about the sensitivity of asbestos testing:

Q. Have you seen documents that says there's a detectable limit that allows .5 percent asbestos?

> **A. Again, I'm not opining on issues related to testing.**
>
> Q. Okay. Except for the 60 out of—out of 80 pages where you talk about asbestos testing?
>
> . . .
>
> A. Okay.
>
> Q. Except for those?
>
> A. I'm—I'm opining in the larger sense . . . of the fact that the test—that testing was created, that multiple levels of testing were created, that the—that the—that in addition to J4-1, **J&J went beyond the industry standard since the 1970s.**
>
> Q. And you can't tell me how much talc was actually tested in five decades, can you?
>
> A. I'm not a toxicologist . . . or a microscopist.

Id. at 399:14–400:16.

VI. Dr. Sutcliffe's opinions lack fit to the facts of this litigation, and at the very least should be cabined to the time period she actually analyzed: the 1970s.

Expert opinions are admissible only to the extent they would "help the trier of fact to understand the evidence or to determine a fact in issue." Rule 702(a). "The expert's testimony must 'fit,' and admissibility depends, in part, on a connection between the expert opinion offered and the particular disputed factual issues in the case." *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999).

There are two reasons Dr. Sutcliffe's testimony does not fit the issues in the case.

The first is—and Plaintiffs humbly hope this position is already clear—that "sensemaking" is not on trial and it has no relevance or fit to any issue in the litigation.

Dr. Sutcliffe struggled to explain her relevance to this litigation in any way other than platitudes.

> Q. Obviously, if we were in court and the judge asks you, Judge, what is your—"Doctor, what is your opinion and why are you even relevant to this case?" What would you say?
>
> . . .
>
> A. Because I am an organization scientist, and I have studied whether the company is responsible.
>
> And in my view, based on a scientific methodology that can be applied across disciplines, using thousands of pages of documents, I have demonstrated that this company has taken actions proactively to understand what's in its product and to understand the safety of its product.

(Ex. 2, Sutcliffe Dep. 307:16–308:11.) She continued, "I am relevant because I have studied organizations. I understand organizational behavior. I have done it for 40 years." *Id.* at 309:14–16.

But J&J's organizational behavior, J&J's ability to engage in Dr. Sutcliffe's "iterative" "sensemaking," J&J's pure-hearted feelings about the "wellbeing" of

women—these are not the bases of Plaintiffs' claims. The claims in this MDL are product liability claims. They turn, as always, on the presence of a defect in J&J's products at the time those products left J&J's hands, which defect made the products unreasonably dangerous. Those questions are answerable by straightforward reference to hard sciences: toxicology; medicine; epidemiology; material science; the science of consumer warnings. J&J never hired a "sensemaker" to advise it and Dr. Sutcliffe pointed to no FDA-regulated company that ever hired her either. What Dr. Sutcliffe attempts to do may be interesting to students of corporate psychoanalysis, but it does not turn her into a Swiss Army knife expert who can testify on anything and everything that involves the "making of sense" inherent in running every business every day.

The second reason is her extreme focus solely on the 1970s. Again, not to belabor the point, but Dr. Sutcliffe's own testimony is that J&J gave up on "sensemaking" after the 1970s "disruptive ambiguity" ended. At the very least, by her own admission, if she is permitted to testify, she should be limited to the year 1979 and prior.

VII. Conclusion.

Dr. Sutcliffe's opinions should be excluded from this litigation in their entirety. Barring that, she should be limited to testifying solely in her field; she should be precluded from offering opinions in scientific fields where she does not

possess credentials; her opinions regarding asbestos testing should be excluded; and she should not be permitted to testify as to events after 1979.

Respectfully submitted,

/s/ *Michelle A. Parfitt*
Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392
mparfitt@ashcraftlaw.com

/s/ *P. Leigh O'Dell*
P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com

Plaintiffs' Co-Lead Counsel

/s/ *Christopher M. Placitella*
Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com

Plaintiffs' Liaison Counsel

PLAINTIFFS' EXECUTIVE COMMITTEE:

Warren T. Burns
BURNS CHAREST LLP
500 North Akard Street, Suite 2810
Dallas, TX 75201
Tel: 469-904-4551
Fax: 469-444-5002
wburns@burnscharest.com

Richard Golomb
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: 215-985-9177
rgolomb@golombhonik.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11thFloor
New York, NY 10017
Tel: 212-397-1000
hunter@napolilaw.com

PLAINTIFFS' STEERING COMMITTEE:

Laurence S. Berman
LEVIN, SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: 215-592-1500
Fax: 215-592-4663
lberman@lfsblaw.com

Timothy G. Blood
BLOOD, HURST & O'REARDON, LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619-338-1100
Fax: 619-338-1101
tblood@bholaw.com

Sindhu S. Daniel
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, #1100
Dallas, TX 75219
Tel: 214-521-3605
Fax: 214-520-1181
sdaniel@baronbudd.com

Jeff S. Gibson
WAGNER REESE, LLP
11939 N. Meridian St.
Carmel, IN 46032
Tel: (317) 569-0000
Fax: (317) 569-8088
jgibson@wagnerreese.com

Kristie M. Hightower
LUNDY, LUNDY, SOILEAU & SOUTH, LLP
501 Broad Street
Lake Charles, LA 70601
Tel: 337-439-0707

Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel: 856-667-0500
Fax: 856-667-5133

Fax: 337-439-1029
khightower@lundylawllp.com

dlapinski@motleyrice.com

Victoria Maniatis
SANDERS PHILLIPS GROSSMAN, LLC
100 Garden City Plaza, Suite 500
Garden City, NJ 11530
Tel: 516-640-3913
Fax: 516-741-0128
vmaniatis@thesandersfirm.com

Carmen S. Scott
MOTLEY RICE LLC
28 Bridgeside Boulevard
Mount Pleasant, SC 29464
Tel: 843-216-9162
Fax: 843-216-9450
cscott@motleyrice.com

Christopher V. Tisi
LEVIN PAPANTONIO
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7000
ctisi@levinlaw.com